~~APPROVED~~ DRAFT PA Criteria

Initial Approval Date: October 14, 2020
Revised Date: January 20, 2021

CRITERIA FOR PRIOR AUTHORIZATION

Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Eculizumab (Soliris®)
Inebilizumab (Uplizna™)
Satralizumab (Enspryng™)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Medication must be prescribed by, or in consultation with a neurologist.
- If the requested drug is for the treatment of NMOSD, patient must have had a positive serologic test for AQP4-IgG (cell-based assay).[1-3]
- Patient must not be on concurrent therapy with another NMOSD agent listed in Table 1.
- Prescriber must provide the patient's baseline number of relapses experienced in the past 12 months before initiating treatment with the requested agent.

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Table 1.
- Patient must have had a decrease or no increase in the number of clinical relapses in the most recent 12 months after initiating treatment with the requested agent~~since initial approval~~.[4]
- Provider must attest patient is not on concurrent therapy with another NMOSD agent listed in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

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Table 1. FDA-approved age and dosing limits for NMOSD Agents[1-3]

Agents	Indication(s)	Age	Dosing Limits
C5 Complement Inhibitor			
Eculizumab (Soliris®)	Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive	≥ 18 years	~~NMOSD: 1200 mg IV every 2 weeks~~900 mg IV weekly for the first 4 weeks, then 1200 mg IV week 5, then 1200 mg IV every 2 weeks
CD19-directed Cytolytic Antibody			
Inebilizumab-cdon (Uplizna™)	NMOSD in patients who are AQP4 antibody positive	≥ 18 years	300 mg IV, followed by a second 300 mg IV 2 weeks later, then 300 mg IV ~~every~~ 6 months
Interleukin-6 (IL-6) Receptor Antagonist			
Satralizumab-mwge (Enspryng™)	NMOSD in patients who are AQP4 antibody positive	≥ 18 years	120 mg SQ ~~every 4 weeks~~at weeks 0, 2 and 4, followed by 120 mg SQ every 4 weeks

IV – intravenous; SQ - subcutaneous

References

1. Soliris (eculizumab) [prescribing information]. Ann Arbor, MI. Alexion Pharmaceuticals, Inc. ~~June 2019~~November 2020.
2. Uplizna (inebilizumab-cdon) [prescribing information]. Gaithersburg, MD. Viela Bio, Inc. June 2020.
3. Enspryng (satralizumab-mwge) [prescribing information]. South San Francisco, CA. Genentech, Inc. August 2020.
4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. Eur J Neurol. 2010;17(8):1019-32. https://onlinelibrary.wiley.com/doi/full/10.1111/j.1468-1331.2010.03066.x. Accessed October 1, 2020.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE